K060401

510(k) Summary

MAR 15 2006

OFFICIAL CONTACT:	Lisa A. Ewing Regulatory Affairs Specialist MEDRAD, INC. One Medrad Drive Indianola, PA 15051 (412) 767-2400 Ext. 3780
CLASSIFICATION NAME:	Magnetic Resonance Diagnostic Device (21 CFR 892.1000, Product Code MOS)
COMMON NAME(S):	Magnetic Resonance Diagnostic Accessory
PROPRIETARY NAME:	MEDRAD 3.0T eCoil Imaging System
PREDICATE DEVICES:	MEDRAD, INC. 1.5T Pelvic Imaging System Interface Device (K053042) MEDRAD, INC. 3.0T Prostate Imaging System (K051349)
INTENDED USE:	The eCoil Imaging System for the GE 3.0T family of scanners is a receive-only coil intended for use as a Magnetic Resonance Diagnostic Device (MRDD) for high-resolution magnetic resonance imaging, including spectroscopy, of the human prostate and surrounding pelvic tissue. The purpose of the interface device for the eCoil Imaging System is to provide interface and support functions to allow the use of MEDRAD 3.0T disposable endorectal coils with GE 3.0T family of scanner systems and Torso Array coils. Only trained healthcare professionals are intended to operate this device.

DEVICE DESCRIPTION AND COMPARISON TO UNMODIFIED PREDICATE:

The MEDRAD 3.0T eCoil Imaging System maintains a similar intended use, similar operational parameters, similar labeling and is used in a manner similar to the predicate devices.

The following comparison table identifies the similarities and differences between the new device and the predicate devices.

Comparison of Features and Principles of Operation in MEDRAD 1.5T Pelvic Imaging System Interface Device for GE (Predicate), MEDRAD 3.0T Prostate Imaging System Interface Device for Siemens (Predicate) and MEDRAD 3.0T Pelvic Imaging System Interface Device for GE (Proposed)

Feature	(Predicate) MEDRAD 1.5T Pelvic Imaging System Interface Device	(Predicate) MEDRAD 3.0T Prostate Imaging System Interface Device	(Proposed) MEDRAD 3.0T eCoil Imaging System Interface Device
Coil Type	Receive-only surface coil	Receive-only surface coil	Receive-only surface coil
Scanner Interface	1.5T GE Signa EXCITE scanners	3.0T Siemens Trio scanners	3.0T GE family of scanners
Coil Interfaces	MEDRAD 1.5T Endorectal Coils, GE 8- or 12-channel Body Array	MEDRAD 3.0T Endorectal Coils	MEDRAD 3.0T Endorectal Coils, GE 8-channel Torso Array
Decoupling	Active and passive	Active and passive	Active and passive
RF Signal Pre-Amplification	Performed by the interface device for the Endorectal Coil (RF output from Body Array is already preamplified).	Performed by the interface device for the Endorectal Coil	Performed by the interface device for the Endorectal Coil (RF output from Torso Array is already preamplified).
Tuning	Does not require tuning to be set in production since interface device has a preamplifier.	Fixed tuning set in production.	Does not require tuning to be set in production since interface device has a preamplifier.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 15 2006

Ms. Lisa A. Ewing
Regulatory Affairs Specialist
MEDRAD, Inc.
One Medrad Drive
INDIANOLA PA 15051-0780

Re: K060401
Trade/Device Name: MEDRAD 3.0T eCoil Imaging System
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: MOS
Dated: February 14, 2006
Received: February 15, 2006

Dear Ms. Ewing:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K060401

Device Name: MEDRAD 3.0T eCoil Imaging System

Indications for Use:

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
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